Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulation No. 4]

RIN 0960–AF30

Revised Medical Criteria for Evaluating Genitourinary Impairments

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving genitourinary impairments. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The proposed revisions reflect advances in medical knowledge, treatment, and methods of evaluating genitourinary impairments.

DATES: To be sure your comments are considered, we must receive them by October 22, 2004.

ADDRESSES: You may give us your comments by: using our Internet site facility (*i.e.*, Social Security Online) at: *http://policy.ssa.gov/pnpublic.nsf/LawsRegs* or the Federal eRulemaking Portal at *http://www.regulations.gov*; e-mail to *regulations@ssa.gov*; by telefax to (410) 966–2830, or by letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703. You may also deliver them to the Office of Regulations, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, between 8 a.m. and 4:30 p.m. on regular business days. Comments are posted on our Internet site, at *http://policy.ssa.gov/pnpublic.nsf/LawsRegs* or you may inspect them on regular business days by making arrangements with the contact person shown in this preamble.

Electronic Version: The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*. It is also available on the Internet site for SSA (*i.e.*, Social Security Online) at: *http://policy.ssa.gov/pnpublic.nsf/LawsRegs*.

FOR FURTHER INFORMATION CONTACT: Martin Sussman, SSA Regulations Officer, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1767 or TTY (410) 966–5609. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet Web site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

What Programs Would These Proposed Regulations Affect?

These proposed regulations would affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II or title XVI, these proposed regulations would also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act,
- Children of insured workers, and
- Widows, widowers, and surviving divorced spouses (*see* 20 CFR 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or is expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) as described above and that results in . . .
Title II	An adult or a child	The inability to do any substantial gainful activity (SGA).
Title XVI	A person age 18 or older	The inability to do any SGA.
Title XVI	A person under age 18	Marked and severe functional limitations.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent a person from doing any gainful activity or that result in "marked and severe functional limitations" in children seeking SSI payments under title XVI of the Act. Although we publish the listings only in appendix 1 to subpart P of part 404 of our rules, we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are a person age 18 or over, we apply the listings in part A when we assess your claim, and we never use the listings in part B.

If you are a person under age 18, we first use the criteria in part B of the listings. If the listings in part B do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in part A. (*See* §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe. (*See* §§ 404.1526 and 416.926.)

We use the listings only to decide that people are disabled or that they are still disabled. We will never deny your claim or decide that you no longer qualify for benefits because your impairment(s)

does not meet or medically equal a listing. If you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the "sequential evaluation process" that we use to evaluate all disability claims. (*See* §§ 404.1520, 416.920, and 416.924.)

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended based only on any changes in the listings. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled the listings. In these cases, we determine whether you have experienced medical improvement and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. *See* §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule after we decide that you have experienced medical improvement in your condition(s). *See* § 416.994a(b)(2).

Why Are We Proposing To Revise the Listings for the Genitourinary System?

We last published final rules revising the listings for the genitourinary system in the **Federal Register** on December 6, 1985 (50 FR 50068). In that notice, we said that those rules would be effective for 8 years unless we extended them, or revised and issued them again. The current listings for the genitourinary system will no longer be effective on July 1, 2005, unless we extend them, or revise and issue them again.

We are proposing these revisions because we decided to update the medical criteria in the listings and to provide more information about how we evaluate genitourinary impairments.

When Will We Start To Use These Rules?

We will not use these rules until we evaluate the public comments we receive on them, determine whether they should be issued as final rules, and issue final rules in the **Federal Register**. If we publish final rules, we will explain in the preamble how we will apply them, and summarize and respond to the public comments. Until the effective date of any final rules, we will continue to use our current rules.

How Long Would These Rules Be Effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

What Revisions Are We Proposing To Make?

We are proposing to present the listings criteria in a more logical order, and to make the listings easier to use. To do this, we propose to:

- Expand the language in the introductory text (preface) in proposed 6.00 and 106.00 to bring it up to date and to reflect the new listings. We are designating the paragraphs numerically to make it easier to use the proposed listings.
- Add a new section in proposed 6.00 and 106.00 defining important terms in the listings.
- Remove listings that are obsolete due to the fact that dialysis is now initiated earlier in the treatment of chronic renal failure, before some of the associated complications specified in the current listings appear or reach listing-level severity. (We define the medical term "renal" in section 6.00A as pertaining to the kidney. We use "renal" in most of these listings because it is the term that physicians use.) For example, while intractable pruritis still may occur (current listing 6.02C4), you usually will be receiving dialysis for the underlying chronic renal disease, and as such, your impairment will meet listing 6.02A. In addition, treatment modalities for many of the side effects and complications of chronic renal disease have improved.
- Revise listings to reflect current medical practice and to be consistent with the terminology used in other body system listings. For example, in the childhood listings, we would change "Renal transplant" (current listing 106.02D) to "Kidney transplantation."
- Remove reference listings and replace them with guidance in the preface. Reference listings are listings that are met by satisfying the criteria of another listing. For example, current listing 6.02C6 for chronic renal disease with persistent anorexia is a reference listing that requires evaluation under current listing 5.08 for weight loss. Therefore, it is redundant. Instead of using a reference listing, we propose to provide general guidance in the preface to the listings (proposed 6.00H), stating that resulting impairments should be evaluated under the criteria for the affected body system.
- Redesignate the listings in part B to correspond with listings addressing the same impairments in part A. Except for minor changes to refer to children, we have repeated much of the language of proposed 6.00 in proposed 106.00. This is because the same basic rules for establishing and evaluating the existence and severity of genitourinary impairments in adults also apply to children.
- Add a listing in part B, proposed listing 106.07, to address congenital genitourinary impairments that are not addressed in listings 106.02 or 106.06.

We also propose to make nonsubstantive editorial changes to update the medical terminology in the listings and to make the language clearer.

How Are We Proposing To Change the Introductory Text to the Listings for Evaluating Genitourinary Impairments in Adults?

6.00 Genitourinary Impairments

We propose to change the name of this body system from Genito-Urinary System to Genitourinary Impairments to more accurately reflect that we use these listings to evaluate genitourinary impairments in accordance with the requirements of the disability program. Even though we recognize that we list only kidney impairments in part A of the listings, we believe it is preferable to use the same heading in part A and part B of the listings, and since kidney impairments are types of genitourinary impairments, we believe this heading is appropriate.

We propose to expand and reorganize the introductory text to these listings to provide additional guidance and to reflect the new listings. The proposed changes to the preface should also improve clarity and readability. The following is a detailed explanation of the proposed rules.

Proposed 6.00A—What Impairments Do These Listings Cover?

In this new section, we explain that we use these listings to evaluate genitourinary impairments resulting from chronic renal disease. Proposed 6.00A2 replaces the parenthetical statement in current listing 6.02, giving examples of chronic renal disease that can lead to renal dysfunction. Proposed 6.00A3 explains that we use the criteria in listing 6.06 to evaluate nephrotic syndrome due to glomerular disease.

Proposed 6.00B—What Do We Mean by the Following Terms?

In proposed 6.00B, we define what we mean by important terms in these listings.

Proposed 6.00C—What Evidence Do We Need?

In proposed 6.00C1, we expand and clarify the documentation requirements discussed in current 6.00A.

In proposed 6.00C2, we explain that we need a longitudinal clinical record covering a period of at least 3 months of observations and treatments, unless we can make a fully favorable determination or decision without it.

We also explain that the record should include laboratory findings, such as serum creatinine or serum albumin values, obtained on more than one examination over at least a 3-month period.

Proposed 6.00C3 corresponds to current 6.00C. We explain that laboratory findings should include pre-dialysis renal function.

Proposed 6.00C4 and 6.00C5 correspond to current 6.00B, which discusses nephrotic syndrome. We clarify the language and specify appropriate laboratory evidence. In the last sentence of proposed 6.00C5, we clarify the documentation requirements in the absence of a pathology report. We did not retain the last sentence of current 6.00B, which explains how we consider complications of nephrotic syndrome such as severe orthostatic hypotension, recurrent infections or venous thromboses; however, proposed 6.00D2 addresses these complications of nephrotic syndrome.

Proposed 6.00D—How Do We Consider the Effects of Treatment?

In this new section, we set forth our policy concerning treatment, including your response to treatment, its efficacy, and any adverse consequences.

Proposed 6.00E—What Other Things Do We Consider When We Evaluate Chronic Renal Disease Under These Listings?

In this new section, proposed 6.00E1 explains that if you have a kidney transplant, we will consider you disabled for 12 months following the surgery. We explain further that we will determine whether your disability is ongoing based upon any residual impairment(s), as shown by signs, symptoms, and laboratory findings, following the first year after the date of transplantation.

In proposed 6.00E2, we explain what the longitudinal clinical record should include in order for us to evaluate nephrotic syndrome.

Proposed 6.00F—What Does the Term Persistent Mean in These Listings?

In proposed 6.00F, we explain that the term persistent in these listings means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been at, or is expected to be at, the level specified in the listing for a continuous period of at least 12 months.

Proposed 6.00G—How Do We Evaluate Specific Genitourinary Listings?

In this new section, we provide additional information on the documentation requirements for three specific listings: 6.02A, Chronic hemodialysis or peritoneal dialysis; 6.02C1, Renal osteodystrophy; and 6.02C2, Persistent motor or sensory neuropathy.

Proposed 6.00H—How Do We Evaluate Impairments That Do Not Meet One of the Genitourinary Listings?

In this new section, we state our basic adjudicative principle that if your impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether or not you are disabled.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Genitourinary Impairments in Adults?

6.01 Category of Impairments, Genitourinary Impairments.

Proposed Listing 6.02—Impairment of Renal Function

We propose to remove the examples listed in the parenthetical statement under the heading for this listing because we address them in proposed 6.00A, making their inclusion in the listing redundant.

Proposed listing 6.02A, Chronic hemodialysis or peritoneal dialysis, corresponds to current listing 6.02A, except that we propose to remove the statement "necessitated by irreversible renal failure" because it is redundant.

Proposed listing 6.02B corresponds to current listing 6.02B, except that we propose to change the name to "kidney transplantation" to be consistent with the terminology used in other body system listings.

Proposed listing 6.02C corresponds to current listing 6.02C, except that we propose to remove the word "severe" from the phrase describing bone pain, and to replace the word "marked" with the word "significant" in the phrase describing osteoporosis in proposed listing 6.02C1, Renal osteodystrophy. We use the term "severe" in our regulations to describe a measure of functional limitations. An impairment is "severe" if it significantly limits an individual's physical or mental ability to do basic work activities. Renal osteodystrophy with bone pain is always a "severe" impairment. We also use the term "marked" in our regulations to describe a measure of functional limitations, and to avoid confusion with our use of "marked" in these regulations, we are replacing it with "significant." However, we are not changing the degree of osteoporosis required to meet this listing.

We propose to remove current listings 6.02C2, A clinical episode of pericarditis, and 6.02C4, Intractable pruritus, because current treatment for most individuals with chronic renal disease includes the initiation of dialysis earlier in the course of treatment. Previously, dialysis would be delayed and the individual would be maintained on a low protein diet. However, now it is known that the long-term prognosis improves for individuals when dialysis is initiated earlier in the course of treatment. Therefore, if you have pericarditis or intractable pruritus, you usually will be receiving dialysis and your impairment will satisfy the criteria in proposed listing 6.02A.

Because of the proposal to remove current listing 6.02C2, we would redesignate current listing 6.02C3, Persistent motor or sensory neuropathy, as proposed listing 6.02C2.

We propose to reorganize current listing 6.02C5, Persistent fluid overload syndrome, and to redesignate it as listing 6.02C3. In addition, we propose that there must be persistent symptoms and signs of congestion despite therapy when considering vascular congestion. Symptoms and signs may include shortness of breath, edema, ascites, and pleural effusion demonstrated on imaging studies.

We propose to remove current listing 6.02C6, Persistent anorexia, since it is a reference listing and we are removing such listings. We have proposed guidance in the preface on evaluating an impairment(s) when it is more appropriately addressed under the affected body system.

We also propose to remove current listing 6.02C7, Persistent hematocrits of 30 percent or less, because hematocrits at this level do not necessarily correlate with an inability to do any gainful activity. An individual with chronic renal disease generally will tolerate hematocrit levels persistently at 30 percent or less.

This does not preclude us from finding you disabled if you have chronic renal disease and persistently low

hematocrit levels. As we discuss in proposed 6.00H, we must consider whether your impairment(s) satisfies the criteria of any appropriate listing. If your impairment(s) does not meet a listing, we will determine whether it medically equals a listing. If your impairment(s) does not meet or medically equal a listing, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process as described in §§ 404.1520 and 416.920. We will consider the facts of your individual case, including your symptoms, such as fatigue and weakness, which may limit your functioning.

Proposed Listing 6.06—Nephrotic Syndrome

We propose to remove the word "significant" from the description of anasarca. Anasarca is, by definition, significant.

How Are We Proposing To Change the Preface to the Listings for Evaluating Genitourinary Impairments in Children?

106.00 Genitourinary Impairments

As in proposed 6.00 in the adult rules, we propose to change the name of this body system to "Genitourinary Impairments."

We propose to add a new section 106.00H to explain how we evaluate episodic genitourinary impairments in children. We also propose to add a new section 106.00I to explain what we mean by "systemic infection," a criterion we use in proposed listing 106.07B.

We also propose to repeat much of the preface of proposed 6.00 in the preface to proposed 106.00, except for minor changes that are specific to the childhood listings. This is because the same basic rules for establishing and evaluating the existence and severity of genitourinary impairments in adults also apply to children. Because we already have described these provisions under the explanation of proposed 6.00ff, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation specific to the evaluation of children's claims.

Proposed 106.00A—What Impairments Do These Listings Cover?

In this section, we provide general guidance on evaluating chronic renal disease or renal dysfunction and congenital genitourinary impairments in children. We propose changes to this section to give additional information about types of renal and urinary tract impairments that are specific to children. For example, we explain that we use the criteria in proposed listing 106.07 to evaluate congenital genitourinary impairments and give examples of such impairments.

Proposed 106.00G—How Do We Evaluate Specific Genitourinary Listings?

We propose to add guidance for proposed listing 106.07, Congenital genitourinary impairments, to explain some factors that we need to consider when evaluating congenital genitourinary impairments under this proposed listing. We also define hospital admissions as inpatient admissions of at least 24 hours duration.

Proposed 106.00H—How Do We Evaluate Episodic Genitourinary Impairments?

In this new section, we explain that some episodic genitourinary impairments will meet a listing when the longitudinal clinical record shows that at least three events have occurred within a consecutive 12-month period, with intervening periods of improvement. These events include surgical procedures, hospitalizations, and treatment with parenteral antibiotics. The occurrence of these events within the specified time period serves to support the severity and chronicity of the underlying impairment(s).

We also indicate that in every listing in which we require more than one event, there must be at least 1 month between the events. We propose this requirement to ensure that we are evaluating separate episodes.

Proposed 106.00I—What Do We Mean By Systemic Infection?

In this section, we explain that the criterion for systemic infection in listing 106.07B means an infection requiring an initial course of parenterally administered antibiotics occurring at least once every 4 months or at least 3 times a year. This chronicity supports the severity required for this listing.

Proposed 106.00J—How Do We Evaluate Impairments That Do Not Meet One of the Genitourinary Listings?

In this section, we repeat the guidelines used in 6.00H, but we include the definition of disability for children who claim SSI payments.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Genitourinary Impairments in Children?

106.01 Category of Impairments, Genitourinary Impairments

We propose to add a new listing 106.07, Congenital genitourinary impairments, specifically for children. There is no parallel in the adult genitourinary listings because we expect with treatment that these impairments will have been resolved before a child reaches adulthood. We also propose to redesignate the childhood listings to be consistent with the adult listings. Because of this, the numbers of the proposed childhood listings are not consecutive.

Proposed Listing 106.02—Impairment of Renal Function

In proposed listing 106.02, we propose to change the heading to make it consistent with the proposed adult criteria.

We also propose to reorder the sequence of disorders included under listing 106.02 to more closely follow the order as those in proposed listing 6.02. Thus:

- Proposed listing 106.02A, Chronic hemodialysis or peritoneal dialysis, would replace current listing 106.02C.
- Proposed listing 106.02B, Kidney transplantation, would replace current listing 106.02D.
- Proposed listing 106.02C, Persistent elevation of serum creatinine, would replace current listing 106.02A.
- Proposed listing 106.02D, Reduction of creatinine clearance, would replace current listing 106.02B.

Proposed Listing 106.06—Nephrotic Syndrome

In proposed listing 106.06, Nephrotic syndrome, we specify that anasarca must persist despite at least 3 months of prescribed therapy. Anasarca, rather than edema, is a more accurate term to define this criterion.

In proposed listing 106.06B, we are revising the terminology in current listing 106.06B for measuring proteinuria to reflect current medical practice. This revision does not make the criteria more stringent. Rather, it is a more appropriate method of measuring proteinuria in children and is equivalent to the measurements used in current listing 106.06B.

Proposed Listing 106.07—Congenital Genitourinary Impairments

In this proposed new listing, we provide criteria that include consideration of repeated surgical

procedures, episodic systemic infections requiring parenteral antibiotics, and episodes of electrolyte disturbance requiring repeated hospitalizations.

Clarity of These Proposed Rules

Executive Order (E.O.) 12866, as amended by E.O. 13258, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand. For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the requirements for a significant regulatory action under E.O. 12866, as amended by E.O. 13258. Thus, they were subject to OMB review.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they would affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed rules contain reporting requirements at 6.00C, 6.00E, 6.00G, 106.00C, 106.00E and106.00G. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burdens referenced in these rules because they were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Comments should be submitted and/or faxed to the Office of Management and Budget and to the Social Security Administration at the following addresses/numbers: Office of Management and Budget, Attn: Desk Officer for SSA, Fax Number: 202–395–6974; Social Security Administration, Attn: SSA Reports Clearance Officer, Rm: 1338 Annex Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, 410–965–6400.

Comments can be received for up to 60 days after publication of this notice and will be most useful if received within 30 days of publication. To receive a copy of the OMB clearance package, you may call the SSA Reports Clearance Officer on 410–965–0454.

List of References

We consulted the following sources when developing these proposed rules:

Richard J. Johnson and John Feehally, Eds., Comprehensive Clinical Nephrology, (London: Mosby, 2000).

Anthony Fauci, et al., *Harrison's Principles of Internal Medicine,* (15th ed., New York: McGraw-Hill, 2001).

John P. Gearhart, Richard C. Rink and Pierre D.E. Mouriquand, *Pediatric Nephrology,* (Philadelphia: W.B. Saunders Co., 2001).

S.G. Massry and R. J. Glassock, *Massry & Glassock's Textbook of Nephrology,* (4th ed. Philadelphia: Lippincott Williams & Wilkins, 2000).

Robert W. Schrier, Ed., *Diseases of the Kidney and Urinary Tract,* (7th ed. Philadelphia: Lippincott Williams & Wilkins, 2001).

These references are included in the rulemaking record for these proposed rules and are available for inspection by interested persons by making arrangements with the contact person shown in this preamble.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: May 19, 2004.

Jo Anne B. Barnhart,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)-(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)-(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

PART 404—[AMENDED]

2. Appendix 1 to subpart P of part 404 is amended as follows:

a. Item 7 of the introductory text before part A of appendix 1 is amended by revising the body system name and expiration date.

b. The Table of Contents for part A of appendix 1 is amended by revising the body system name for section 6.00.

c. Section 6.00 of part A of appendix 1 is revised.

d. The Table of Contents for part B of appendix 1 is amended by revising the body system name for section 106.00.

e. Section 106.00 of part B of appendix 1 is revised.

The revised text is set forth as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

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7. Genitourinary impairments (6.00 and 106.00): (*insert date 5 years from the effective date of the final rules*).

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Part A

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6.00 Genitourinary Impairments

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6.00 GENITOURINARY IMPAIRMENTS

A. *What impairments do these listings cover?*

1. We use these listings to evaluate genitourinary impairments resulting from chronic renal disease.

2. We use the criteria in 6.02 to evaluate renal dysfunction due to any chronic renal disease, such as: glomerulonephritis due to hypertensive, diabetic, or metabolic renal disease; interstitial nephritis; renovascular disease; chronic obstructive uropathy; and hereditary nephropathies.

3. We use the criteria in 6.06 to evaluate nephrotic syndrome due to glomerular disease.

B. *What do we mean by the following terms?*

1. *Anasarca* is generalized massive edema (swelling).

2. *Creatinine* is a normal product of muscle metabolism.

3. *Creatinine clearance test* is a test for renal function based on the rate at which creatinine is excreted by the kidney.

4. *Diastolic hypertension* is elevated diastolic blood pressure.

5. *Fluid overload syndrome* associated with renal disease occurs when there is excessive sodium and water retention in the body that cannot be adequately removed by the diseased kidneys. This may contribute to hypertension, congestive heart failure, and sometimes accumulation of fluid in the abdomen (ascites), or chest (pleural effusions).

6. *Glomerular disease* can be classified into two broad categories, nephrotic and nephritic. Nephrotic conditions are associated with increased urinary protein excretion and nephritic conditions are associated with inflammation of the internal structures of the kidneys.

7. *Hemodialysis*, or *dialysis*, is the removal of toxic metabolic byproducts from the blood by diffusion in an artificial kidney machine.

8. *Motor neuropathy* is neuropathy or polyneuropathy involving only the motor nerves.

9. *Nephrotic syndrome* is a general name for a group of diseases involving defective kidney glomeruli, characterized by massive proteinuria and lipiduria with varying degrees of edema, hypoalbuminemia, and hyperlipidemia.

10. *Neuropathy* is a problem in peripheral nerve function (any part of the nervous system except the brain and spinal cord) that causes pain, numbness, tingling, swelling, and muscle weakness in various parts of the body.

11. *Osteitis fibrosa* is fibrous degeneration with weakening and deformity of bones.

12. *Osteomalacia* is a softening of the bones.

13. *Osteoporosis* is a thinning of the bones with reduction in bone mass resulting from the depletion of calcium and bone protein.

14. *Pathologic fractures* are fractures resulting from weakening of the bone structure by pathologic processes, such as osteomalacia, osteomyelitis, and other diseases.

15. *Peritoneal dialysis* is a method of hemodialysis in which the dialyzing solution is introduced into and removed from the peritoneal cavity either continuously or intermittently.

16. *Proteinuria* is excess protein in the urine.

17. *Renal* means pertaining to the kidney.

18. *Renal osteodystrophy* is a variety of bone disorders usually caused by chronic kidney failure.

19. *Sensory neuropathy* is neuropathy or polyneuropathy that involves only the sensory nerves.

20. *Serum albumin* is a major plasma protein that is responsible for much of the plasma colloidal osmotic pressure and serves as a transport protein.

21. *Serum creatinine* is the amount of creatinine in the blood and is measured to evaluate kidney function.

C. *What evidence do we need?*

1. We need a longitudinal record of your medical history that includes records of treatment, response to treatment, hospitalizations, and laboratory evidence of renal disease that indicates its progressive nature. The laboratory or clinical evidence will indicate deterioration of renal function, such as elevation of serum creatinine.

2. We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as serum creatinine values, obtained on more than one examination over the 3-month period.

3. When you are undergoing dialysis, we should have laboratory findings showing your renal function before you started dialysis.

4. The medical evidence establishing the clinical diagnosis of nephrotic syndrome must include a description of the extent of edema, including pretibial, periorbital, or presacral edema. If present, the medical evidence should describe any ascites, pleural effusion, or pericardial effusion. Levels of serum albumin and proteinuria must be included.

5. If a renal biopsy has been performed, the evidence should include a copy of the report of the microscopic examination of the specimen. However, if we do not have a copy of the microscopic examination in the evidence, we can accept a statement from an acceptable medical source that a biopsy was performed, with a description of the results.

D. *Do we consider the effects of treatment?* We consider factors such as the:

1. Type of therapy.
2. Response to therapy.
3. Side effects of therapy.
4. Effects of any post-therapeutic residuals.
5. Expected duration of treatment.

E. *What other things do we consider when we evaluate chronic renal disease under these listings?*

1. *Kidney transplantation.* If you have undergone kidney transplantation, we will consider you to be disabled for 12 months following the surgery because, during the first year, there is a greater likelihood of rejection of the organ and recurrent infection. After the first year posttransplantation, we will base continuing disability evaluation upon the residual impairment as shown by symptoms, signs, and laboratory findings. We will include absence of symptoms, signs, and laboratory findings indicative of kidney dysfunction in our consideration of whether medical improvement (as defined in §§ 404.1579(b)(1) and (c)(1), 404.1594(b)(1) and (c)(1), 416.994(b)(1)(i) and (b)(2)(i), or 416.994a as appropriate) has occurred. We will consider any residual impairment arising from:

a. The occurrence of rejection episodes.
b. The use of immunosuppressants.
c. Frequent renal infections.
d. Side effects of corticosteroids.
e. The presence of systemic complications such as other infections, neuropathy, or deterioration of other organ systems.

2. *Nephrotic syndrome.* The longitudinal clinical record should include a description of prescribed therapy, response to therapy, and any side effects of therapy. In order for your nephrotic syndrome to meet 6.06A or B, the medical evidence must document that you have the appropriate laboratory findings required by these listings and that your anasarca has persisted for at least 3 months despite prescribed therapy. However, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in your case record.

F. *What does the term persistent mean in these listings? Persistent* means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been at, or is expected to be at, the level specified in the listing for a continuous period of at least 12 months.

G. *How do we evaluate specific genitourinary listings?*

1. *Chronic hemodialysis or peritoneal dialysis* (6.02A). A report from an acceptable medical source describing the chronic renal disease and the need for ongoing dialysis is sufficient to satisfy the requirements in 6.02A.

2. *Renal osteodystrophy* (6.02C1). This condition is bone deterioration resulting from chronic renal disease. The resultant bone disease includes osteitis fibrosa cystica, osteomalacia, osteoporosis, and osteosclerosis.

3. *Persistent motor or sensory neuropathy* (6.02C2). The longitudinal clinical record must show that the neuropathy is a "severe" impairment as defined in §§ 404.1520(c) and 416.920(c) that has lasted or can be expected to last for a continuous period of at least 12 months.

H. *How do we evaluate impairments that do not meet one of the genitourinary listings?*

1. These listings are only examples of common genitourinary impairments that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system. For example, weight loss associated with chronic renal disease should be evaluated under 5.08.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing(s). (See §§ 404.1526 and 416.926.) If you have an impairment(s) that does not meet or medically equal the criteria of the listings, you may or may not have the residual functional capacity to engage in substantial gainful activity. Therefore, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether you continue to be disabled, we use the rules in §§ 404.1579(b)(1) and (c)(1), 404.1594(b)(1) and (c)(1), 416.994(b)(1)(i) and (b)(2)(i), or 416.994a as appropriate.

6.01 Category of Impairments, Genitourinary Impairments

6.02 *Impairment of renal function,* due to any chronic renal disease expected to last 12 months. With:

A. *Chronic hemodialysis or peritoneal dialysis* (see 6.00G1);

or

B. *Kidney transplantation.* (See 6.00E1.) Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment;

or

C. *Persistent elevation of serum creatinine* to 4 mg per dL (100 ml) or greater or *reduction of creatinine clearance* to 20 ml per minute or less, over at least 3 months, with one of the following:

1. Renal osteodystrophy (see 6.00G2) manifested by bone pain and appropriate medically acceptable imaging demonstrating abnormalities such as osteitis fibrosa, significant osteoporosis, osteomalacia, or pathologic fractures;

or

2. Persistent motor or sensory neuropathy (see 6.00G3);

or

3. Persistent fluid overload syndrome with:

a. Diastolic hypertension greater than or equal to diastolic blood pressure of 110 mm Hg; or

b. Persistent symptoms and signs of vascular congestion despite prescribed therapy.

6.06 *Nephrotic syndrome,* with anasarca, persistent for at least 3 months despite prescribed therapy (see 6.00E2). With:

A. Serum albumin of 3.0 g per dL (100 ml) or less and proteinuria of 3.5 g or greater per 24 hours;

or

B. Proteinuria of 10.0 g or greater per 24 hours.

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Part B

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106.00 Genitourinary Impairments

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106.00 GENITOURINARY IMPAIRMENTS

A. *What impairments do these listings cover?*

1. We use these listings to evaluate genitourinary impairments resulting from chronic renal disease and congenital genitourinary disorders.

2. We use the criteria in 106.02 to evaluate renal dysfunction due to any chronic renal disease, such as: glomerulonephritis due to hypertensive, diabetic, or metabolic renal disease; interstitial nephritis; renovascular disease; chronic obstructive uropathy; and hereditary nephropathies.

3. We use the criteria in 106.06 to evaluate nephrotic syndrome due to glomerular disease.

4. We use the criteria in 106.07 to evaluate congenital genitourinary impairments such as ectopic ureter, urethral valves, and neurogenic bladder.

B. *What do we mean by the following terms?*

1. *Anasarca* is generalized massive edema (swelling).

2. *Creatinine* is a normal product of muscle metabolism.

3. *Creatinine clearance test* is a test for renal function based on the rate at which creatinine is excreted by the kidney.

4. *Glomerular disease* can be classified into two broad categories, nephrotic and nephritic. Nephrotic conditions are associated with increased urinary protein excretion and nephritic conditions are associated with inflammation of the internal structures of the kidneys.

5. *Hemodialysis,* or *dialysis,* is the removal of toxic metabolic byproducts from the blood by diffusion in an artificial kidney machine.

6. *Nephrotic syndrome* is a general name for a group of diseases involving defective kidney glomeruli, characterized by massive proteinuria and lipiduria with varying degrees of edema, hypoalbuminemia, and hyperlipidemia.

7. *Neuropathy* is a problem in peripheral nerve function (any part of the nervous system except the brain and spinal cord) that causes pain, numbness, tingling, swelling, and muscle weakness in various parts of the body.

8. *Parenteral antibiotics* refer to the administration of antibiotics by intravenous, intramuscular, or subcutaneous injection.

9. *Peritoneal dialysis* is a method of hemodialysis in which the dialyzing solution is introduced into and removed from the peritoneal cavity either continuously or intermittently.

10. *Proteinuria* is excess protein in the urine.

11. *Renal* means pertaining to the kidney.

12. *Serum albumin* is a major plasma protein that is responsible for much of the plasma colloidal osmotic pressure and serves as a transport protein.

13. *Serum creatinine* is the amount of creatinine in the blood and is measured to evaluate kidney function.

C. *What evidence do we need?*

1. We need a longitudinal record of your medical history that includes records of treatment, response to treatment, hospitalizations, and laboratory evidence of renal disease that indicates its progressive nature or of congenital genitourinary impairments that documents their recurrent or episodic nature. The laboratory or clinical evidence will indicate deterioration of renal function, such as elevation of serum creatinine, or changes in genitourinary function, such as episodes of electrolyte disturbance.

2. We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as serum creatinine values, obtained on more than one examination over the 3-month period.

3. When you are undergoing dialysis, we should have laboratory findings showing your renal function before you started dialysis.

4. The medical evidence establishing the clinical diagnosis of nephrotic syndrome must include a description of the extent of edema, including pretibial, periorbital, or presacral edema. If present, the medical evidence should describe any ascites, pleural effusion, or pericardial effusion. Levels of serum albumin and proteinuria must be included.

5. If a renal biopsy has been performed, the evidence should include a copy of the report of the microscopic examination of the specimen. However, if we do not have a copy of the microscopic examination in the evidence, we can accept a statement from an acceptable medical source that a biopsy was performed, with a description of the results.

6. The medical evidence documenting congenital genitourinary impairments should include treating physician records, operative reports, and hospital records. They should describe the frequency of your episodes, prescribed treatment, laboratory findings, and any surgical procedures performed.

D. *Do we consider the effects of treatment?* We consider factors such as the:

1. Type of therapy.
2. Response to therapy.
3. Side effects of therapy.
4. Effects of any post-therapeutic residuals.
5. Expected duration of treatment.

E. *What other things do we consider when we evaluate chronic renal disease under these listings?*

1. *Kidney transplantation.* If you have undergone kidney transplantation, we will consider you to be disabled for 12 months following the surgery because, during the first year, there is a greater likelihood of rejection of the organ and recurrent infection. After the first year posttransplantation, we will base continuing disability evaluation upon the residual impairment as shown by symptoms, signs, and laboratory findings. We will include absence of symptoms, signs, and laboratory findings indicative of kidney dysfunction in our consideration of whether medical improvement (as defined in §§ 404.1594(b)(1) and (c)(1) and 416.994a, as appropriate) has occurred. We will consider any residual impairment arising from:

a. The occurrence of rejection episodes.
b. The use of immunosuppressants.
c. Frequent renal infections.
d. Side effects of corticosteroids.
e. The presence of systemic complications such as other infections, neuropathy, or deterioration of other organ systems.

2. *Nephrotic syndrome.* The longitudinal clinical record should include a description of prescribed therapy, response to therapy, and any side effects of therapy. In order for your nephrotic syndrome to meet 106.06A or B, the medical evidence must document that you have the appropriate laboratory findings required by these listings and that your anasarca has persisted for at least 3 months despite prescribed therapy. However, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in your case record.

F. *What does the term persistent mean in these listings? Persistent* means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been at, or is expected to be at, the level specified in the listing for a continuous period of at least 12 months.

G. *How do we evaluate specific genitourinary listings?*

1. *Chronic hemodialysis or peritoneal dialysis* (106.02A). A report from an acceptable medical source describing the chronic renal disease and the need for ongoing dialysis is sufficient to satisfy the requirements in 106.02A.

2. *Congenital genitourinary impairments* (106.07).

a. The criteria include the need for repeated surgeries, recurrent infection, and electrolyte imbalance.

b. Diagnostic cystoscopy does not satisfy the requirement for repeated surgical procedures.

c. Appropriate laboratory and clinical evidence document electrolyte disturbance.

d. Hospital admissions are inpatient hospitalizations for 24 hours or more.

H. *How do we evaluate episodic genitourinary impairments?* Some listings for genitourinary impairments are met when the longitudinal clinical record shows that at least three events have occurred within a consecutive 12-month period, with intervening periods of improvement. *Events* include urological surgical procedures, hospitalizations, and treatment with parenteral antibiotics. In every listing in which we require more than one event, there must be at least 1 month between the events, in order to ensure that we are evaluating separate episodes.

I. *What do we mean by systemic infection? Systemic infection* (106.07B) is an infection requiring an initial course of parenterally administered antibiotics occurring at least once every 4 months or at least 3 times a year. *See* 106.00H for information about how we evaluate episodic genitourinary impairments.

J. *How do we evaluate impairments that do not meet one of the genitourinary listings?*

1. These listings are only examples of common genitourinary impairments that we consider severe enough to prevent you from doing any gainful activity or that result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing(s), or, in the case of a claim for SSI payments, functionally equals the listings. (*See* §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a.

106.01 Category of Impairments, Genitourinary Impairments

106.02 *Impairment of renal function,* due to any chronic renal disease expected to last 12 months. With:

A. *Chronic hemodialysis or peritoneal dialysis* (*see* 106.00G1);

or

B. *Kidney transplantation.* (*See* 106.00E1.) Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment;

or

C. *Persistent elevation of serum creatinine* to 3 mg per deciliter (100 ml) or greater, over at least 3 months;

or

D. *Reduction of creatinine clearance* to 30 ml per minute (43 liters/24 hours) per 1.73 m^2 of body surface area over at least 3 months.

106.06 *Nephrotic syndrome,* with anasarca, persistent for at least 3 months despite prescribed therapy. (*See* 106.00E2.) With:

A. Serum albumin of 2.0 g/dL (100 ml) or less;

or

B. Proteinuria of 40 $mg/m^2/hr$ or greater.

106.07 *Congenital genitourinary impairments* (*see* 106.00G3 and 106.00H) resulting in one of the following:

A. Repeated urological surgical procedures, occurring at least 3 times in a consecutive 12-month period;

or

B. Documented episodes of systemic infection requiring an initial course of parenteral antibiotics, occurring at least 3 times in a consecutive 12-month period (*see* 106.00I);

or

C. Hospitalization (for 24 hours or more) for episodes of electrolyte disturbance, occurring at least 3 times in a consecutive 12-month period.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 18 and 75

RIN 1219–AB34 and RIN 1219–AA98

High-Voltage Continuous Mining Machines and Low- and Medium-Voltage Diesel-Powered Electrical Generators

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Change of hearing dates and locations; close of comment periods.

SUMMARY: This document announces changes in the dates and locations of the public hearings for the proposed rules addressing (1) High-Voltage Continuous Mining Machines; and (2) Low- and Medium-Voltage Diesel Powered Electrical Generators. The hearings for both proposed rules have been rescheduled for November 2004. The hearings in Pittsburgh, Pennsylvania have been moved to Morgantown, West Virginia.

The hearings for the High-Voltage Continuous Mining Machines (HVCM) proposed rule will be held first, starting at 9 a.m. local time each day; and the hearings for the proposed rule for Low- and Medium-Voltage Diesel PoweredElectrical Generators will follow.

DATES: The post-hearing comment period for both proposed rules will close on December 10, 2004.

The public hearing dates and locations are listed in the Public Hearing Section under **SUPPLEMENTARY INFORMATION** below. Individuals or organizations wishing to make oral presentations for the record should submit a request at least 5 days prior to the hearing dates. However, commenters do not need to submit a request in advance in order to speak at the hearing.

ADDRESSES: You may submit comments, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *Comments@MSHA.gov.* You must include the Regulatory Identification Number (RIN) in the subject line for each rule you are commenting on. For comments on the proposed rule addressing Low- and Medium-Voltage Diesel Powered Electrical Generators include RIN 1219–AA98 in the subject line of the message. To submit comments for the proposed rule addressing High-Voltage Continuous Mining Machines include RIN 1219–AB34 in the subject line.
- Fax: (202) 693–9441.
- Mail/Hand Delivery/Courier: MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2313, Arlington, Virginia 22209–3939.

Instructions: All submissions must reference MSHA and RIN numbers 1219–AA98 for the proposed rule addressing Low—and Medium-Voltage Diesel Powered Electrical Generators or RIN 1219-AB34 for the proposed rule addressing High-Voltage Continuous Mining Machines.

Docket: To access comments received, go to *http://www.MSHA.gov* or MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia. All comments received will be posted without change to *http://www.msha.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939. Mr. Nichols can be reached at nichols.marvin@dol.gov (Internet E-mail), (202) 693–9440 (voice), or (202) 693–9441 (facsimile). This notice is available on the Internet